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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/824,459 | 04/13/2004 | Stephen L. Monfre | SENS0021 | 6605 |

22862 7590 04/27/2007
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| EXAMINER |
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BERHANU, ETSUB D

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| ART UNIT | PAPER NUMBER |
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3768

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/27/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/824,459

Applicant(s)

MONFRE ET AL.

Examiner

Etsub D. Berhanu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23,26-31 and 40 is/are allowed.
- 6) ☒ Claim(s) 1-22,24,25 and 32-39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION***Priority***

1. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where

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there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Objections

2. Claims 1, 8, 18 and 28 are objected to because of the following informalities: the term - - as - - should be inserted between the terms “acts” and “an” in line 14 of claim 1; the term “the” in line 2 of claims 8 and 28 should be amended to read - - a - - in order to provide proper antecedent basis; the term “to” in line 1 of claim 18 should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 discloses a method of delivering optical coupling fluid to a sampling site, but fails to disclose any further structural limitation to the claimed invention.

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Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 discloses the limitations “said contact surface being in contact with said sampling skin” in lines 6-7 and “said outer surface being in direct contact with said sampling site” in lines 12-13, and thus improperly recites human tissue as part of the claimed invention. Claim 9 discloses the limitation “said optical probe is coupled into said aperture and has direct contact with said sampling site” in line 4, and thus improperly recites human tissue as part of the claimed invention. Claim 10 discloses the limitation “said optical probe is coupled into said aperture and has direct contact with said sampling site” in lines 4-5, and thus improperly recites human tissue as part of the claimed invention. Claim 11 discloses the limitation “said optical probe is coupled into said aperture and has direct contact with said sampling site” in lines 1-2, and thus improperly recites human tissue as part of the claimed invention. It is suggested that Applicant amend the claims to include the phrase “adapted to be in contact with” or “configured to be in contact with” in order to eliminate human tissue as part of the claimed invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4, 5, 21, 22, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Roper et al.’373 (USPN 5,879,373).

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Figure 1A of Roper et al.'373 discloses a placement guide for coupling an optical noninvasive glucose analyzer (20), the optical probe comprising an optical incident member (13) and an optical collection member (14), the guide comprising: a mount (20) having a contact surface (21) configured to be in contact with a sampling skin; an aperture (29) defined by the mount that houses an evenly flat, insulating, near-IR transmissive hydration inducing plug (28) and which is adapted to receive the optical probe, wherein the hydration inducing plug has an outer surface (a first layer) in direct contact with the sampling site and acts as an optical interface between the optical probe and the sampling site when the optical probe is coupled into the aperture and a second layer facing the optical incident and collection members. Roper et al.'373 also discloses a method of collecting data used in determining glucose concentration (col. 2, lines 63-66) wherein the method comprises coupling an optical probe of a noninvasive glucose analyzer with a placement guide such as the one described above, delivering incident photons into a sampling site in sampling skin and collecting photons emerging from the sampling site (see claim 1 of Roper et al.'373).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 12-19 and 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roper et al.'373, as applied to claims 1 and 21, further in view of Wu et al.'671 (US Pub. No. 2002/0055671) further in view of Chance'987 (USPN 5,596,987).

Roper et al.'373 discloses all the elements of the current invention, as discussed in paragraph 7 above, except for the mount comprising a reservoir for containing an optical coupling fluid, the reservoir

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being connected to one or more channels via which the optical coupling fluid is lead to a sampling site. Wu et al.'671 discloses that the use of optical coupling fluids to improve measurement precision and accuracy of optical measurements is well known in the art (page 1, section [0009]). Chance'987 teaches the use of an optical probe having a mount with channels attached to a reservoir containing optical coupling fluid, wherein the optical coupling fluid is channeled to a sampling site in order to provide more accurate optical measurements (see Figure 4A and description thereof in col. 11, lines 17-35). Chance'987 further teaches that the optical probe is capable of measuring glucose concentration (col. 2, lines 59-61). While Chance'987 teaches the use of an optically matched coupling fluid, it fails to disclose the details of the fluid. Wu et al.'671 discloses the use of chlorofluorocarbons as a suitable optical index matching coupling fluid (page 7, section [0071]). It would have been within the skill of the art to use a chlorofluorocarbon optical index matching fluid, as taught by Wu et al.'671, as the optical index matching fluid of Chance'987 since the apparatus and method of Chance'987 requires an optical index matching fluid, but fails to disclose the details of the optical index matching fluid, and Wu et al.'671 discloses details of an optical index matching fluid. Further, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the apparatus and method of Roper et al.'373 to include a mount having a reservoir for containing optical coupling fluid, wherein the optical coupling fluid is led to a sampling site via channels, as taught by Chance'987, since it would improve measurement precision and accuracy of the glucose measurement.

Allowable Subject Matter

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art teaches or suggests, either alone or in combination, a hydration inducing plug wherein the plug either: is comprised of a fluoropolymer; is comprised of multiple layers with their own physical properties or wherein the multiple layers are unevenly heat compressed so that a central area of the plug is

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thinner than a surrounding area; comprises an aperture formed in its center; has an inner surface shaped as an optical convexity; has a small space maintained between the hydration inducing plug and an optical incident member of an optical probe, wherein an optical collection member of the optical probe is coupled into an aperture of a mount containing the hydration inducing plug; or a mount containing the hydration inducing plug contains three reservoirs containing optical coupling fluid, each of the three reservoirs being placed around a sampling site at approximately the points of an isosceles triangle, in combination with the other claimed elements.

11. Claims 23, 26-31 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDB

ERIC F. WINAKUR
PRIMARY EXAMINER

